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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEBER, JON P

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/859,650

Applicant(s)

ALLBRITTON ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 21-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 17 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Status of the Claims

Claims 1-53 have been presented for examination.

Election/Restrictions

Applicant's election with traverse of group I, claims 1-20 in Paper No. 6, filed 28 April 2003 is acknowledged. The traversal is on the ground(s) that there is no burden between Groups I and II which differ only in the location of where the reaction (detecting oncogenic activity) takes place, small volume or biological cell. This is not found persuasive because burden was established by separate classification in the Office action of 08 April 2003 and because a search of one would not necessarily lead to the other or render it obvious. Further, there are additional steps in Group I, liberating the substrate and altered substrate from the cells, and separating the same, which are not part of the process of Group II and could give rise to elements of patentability.

The requirement is still deemed proper and is therefore made FINAL. Claims 21-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6. It is suggested that the non-elected claims be canceled in response to this Office action to expedite prosecution.

Specification

This application contains sequence disclosures at page 26, 49-50, and 60 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R.

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§ 1.821(a)(1) and (a)(2). However, this application fails to comply with one or more of the requirements of 37 C.F.R. § 1.821 through 1.825 for one or more of the reasons set forth on the "Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequences And/Or Amino Acid Sequence Disclosures" sent with the Office action of 08 April 2003. Wherein attention is directed to paragraph(s) §1.82 (a) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete. Failure to comply a second time will be deemed nonresponsive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites detecting the label to identify the substrate molecules in the penultimate step and determining the presence of the chemical reaction in the ultimate step from the presence of modified substrate. This is inconsistent. The claim is drawn to measuring the presence of the activity, detection, not quantitation. One learns nothing from merely detecting unaltered substrate.

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Claims 2 and 6 recite the limitation "quantifying". There is insufficient antecedent basis for this limitation in the claim. Claim 1 is drawn to measuring the presence, i.e, simple detection. There is no basis for quantitation in simple detection.

Claim 3 recites "comprises catalysis by a kinase". What other things does the chemical reaction comprise besides the kinase catalysis? This is very confusing and unclear. Perhaps closed language would be more clear.

Claim 4 seems redundant. By definition a chemical reaction changes the structure of the molecule, else no chemical change has occurred.

Claim 6 recites the limitation "and" in line 2. There is insufficient antecedent basis for this limitation in the claim. The previous claim recited "and/or".

Claim 7 recites that "disposing" comprising using a naturally occurring substrate within said cell, which is contrary to the art accepted meaning of disposing which requires active intervention. That is if the substrate is already there, no act of disposing has occurred.

In claim 7 it is not clear how substrate molecules containing a label are naturally occurring or induced to be produced within the cell, since the labels are artificially attached to the substrates.

Claim 9 recites "stimulating said cell or cells" which is vague and indefinite because the nature and manner as well as the purpose of the stimulation are not set forth with particularity within the claim.

Claim 10 recites the limitation "comparing" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no basis for comparison of simple detection of activity absent quantitation. The independent claim only provides for detection not quantitation.

Claim 12 recites "exhibit optical absorption" which is vague and indefinite because all chemicals exhibit optical absorption. It is not clear how this is a limitation. Is there a wavelength range of interest, such as visible?

Claim 16 recites the limitation "said modified peptides" in line 2. There is insufficient antecedent basis for this limitation in the claim. Perhaps claim 16 was intended to depend from claim 15.

Claim 20 recites the limitation "plurality" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites "**an** ocogenic protein" – singular.

Prior Art

For the purposes of prior art, benefit to parent applications 09/358,504 and 09/036,706 are not accorded because neither of these applications discloses detecting **oncogenes** as instantly required.

Parent application 09/358,504 discloses and claims a general method of detecting chemical (enzymatic) activity in a cell or cells comprising the identical set of steps as instantly (the last step in claim 1 of 09/358,504 is instant claim 20). One could consider the instant application to be a species of the genus represented by the claims of 09/358,504. The specific examples in 09/358,504 are directed to detecting protein kinases. The instant application identifies oncogenes as usually being protein kinases. Hence, the selection of oncogenes as opposed to other protein kinases is the basis of a second more detailed species-genus relationship. The difference in species is the selection of substrate 1) for enzymes in general and 2) within protein kinases in particular. Given that the patentability of the genus over the art of

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record therein has been established in 09/358,504, it is inevitable that the instant species must be patentable over the art as well.

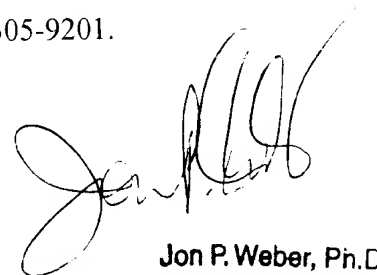
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off first Friday 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4215. The fax phone numbers for the organization where this application or proceeding is assigned are 703-842-9206 for regular communications and 703-842-9207 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9201.

JPW
May 8, 2003



Jon P. Weber, Ph.D
Primary Examiner